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EXAMINER	
BUCKLEY, AUDREA	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,237	GOLZ-BERNER ET AL.	
	Examiner	Art Unit	
	AUDREA J. BUCKLEY	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-24,26,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-24, 26, 30, and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

This action is in response to remarks and amendments filed January 10, 2011. Claims 1-16, 25, and 27-29 are canceled. Claim 17 was amended. No new claims were added. Accordingly, claims 17-24, 26, 30, and 31 are under current examination.

Withdrawn Claim Rejections

The rejection of claims 17, 20, 23, 24, 30, and 31 under 35 U.S.C. 103(a) as being unpatentable over Stora in view of Zastrow et al. is withdrawn in light of Applicants' amendments to the claims filed 1/10/2011. This and subsequent rejections have been clarified below in light of Applicant's amendments.

The rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Stora in view of Zastrow et al. and further in view of Gross et al. '318 is withdrawn in light of Applicants' amendments to the claims filed 1/10/2011.

The rejection of claims 21 and 22 under 35 U.S.C. 103(a) as being unpatentable over Stora in view of Zastrow et al. and further in view of Gross et al. '601 is withdrawn in light of Applicants' amendments to the claims filed 1/10/2011.

The rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Stora in view of Zastrow et al. and further in view of Gross et al. '601 and further in view of Pelle et al. and Nakanishi et al. is withdrawn in light of Applicants' amendments to the claims filed 1/10/2011.

The rejection of claim 26 under 35 U.S.C. 103(a) as being unpatentable over Stora in view of Zastrow et al. and further in view of Lu is withdrawn in light of Applicants' amendments to the claims filed 1/10/2011.

Maintained and New Grounds of Rejection as Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 20, 23, 24, 26, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109, patented Jun. 2002) in view of Zastrow et al. (US 5,961,988, issued Oct. 1999).

Regarding claims 17, 20, 23, 24, 26, and 30, Stora teaches perfume compositions free of organic solvents, existing in emulsified form, and capable of delivering the active agent to the skin (see abstract, in particular). Example 1 teaches a formulation comprising 2.23% perfluorodecaline, a fluorinated hydrocarbon; 24.95% Silicone DC®345, a silicone polymer; and 10.05% of a perfuming oil base; the perfluorodecaline is the oxygen carrier system as in instant claims 17 and 24. As to claim 30, Examples 3 and 4 teach a presence of 55.12% by weight of Silicone DC®345 (a silicone polymer). As to claim 31, Stora teaches topically applicable emulsions with controlled refractive indices and viscosity values. Therefore, these emulsions are formed as topically applicable lotions, creams, or gels (see column 2, lines 3-48).

Regarding claim 17, the embodiments of the invention of Stora do not illustrate a formulation having an oxygen carrier system limited to a presence between 6 and 10% by mass of the total formulation. However, it would have been within the skill of the ordinary artisan to dilute the concentration of the formulations as taught by Stora since the concentration of an oxygen carrier system in a dermatologic formulation is a result effective variable clearly affecting the type of product obtained. See MPEP 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch,* 617 F.2d 272, 205

USPQ 215 (CCPA 1980). In view of this, it would have been within the skill of the artisan to optimize the base formulation presented above prior to application in order to optimize the formulation's efficacy and minimize cost and reasonably to expect success from doing so. This dilution (i.e., in which the formulation of Stora comprises 20% (1/5)) would have involved the application of a known technique, dilution, to maximize efficacy while minimizing cost and negative side effects in order to yield predictable results since the formulation components would have retained their respective known functions upon dilution and subsequent application as a cosmetic or dermatologic formulation. It is noted that a dilution by a factor of five, for example, of Stora's formulation results in a formulation which meets the limitations of the instant claims since Stora teaches similar proportions of fluorinated hydrocarbon, silicone polymer, and oil as instantly recited. More specifically, aqueous dilution of Stora's Example 1 by a factor of five would have resulted in 0.446% by weight of perfluorodecaline, 4.99% by weight of silicone polymer, and 2.01% by weight of perfuming oil base; these values lie within the instantly recited ranges of 0.006-1% of fluorinated hydrocarbon, 0.6-8.5% by weight of silicone polymer, and 0.3-2.5% by weight of oil base, indicating the proportional relationship between the instant claims and the known art and the predictability of the results of this dilution. Similarly, this routine optimization would have been applied further pertaining to the limitations of claims 20, 24, 26, and 30.

Stora does not specify the partial pressure of the oxygen gas in the formulation disclosed. However, Zastrow et al. teach cosmetic and

dermatological formulations comprising phospholipids and fluorocarbons which together form lamellar aggregates which are loaded with oxygen, preferably up to the saturation limit. A preferred partial pressure is in the range of 10 to 40 mPa (80 to 300 mm Hg) (see column 1, lines 35 and 36; column 2, lines 25-28; column 3, lines 29-30 and lines 45-50). Similarly, Zastrow et al. teaches that perfluorinated or highly fluorinated hydrocarbon compounds are included because these compounds are desirably capable of transporting gases such as oxygen (see column 2, lines 58-61).

Both Stora and Zastrow are directed to fluorocarbon containing dermatological formulations. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to load oxygen in the fluorocarbon carrier as taught by Zastrow in the fluorocarbon carriers in the formulations of Stora. One would have been motivated to do so since Zastrow et al. teaches that a preferred oxygen pressure is up to the saturation limit, a value in the range of 80 to 300 mmHg, a range which includes the data points of the instantly recited range and where Zastrow specifies that higher oxygen content is desirable.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Zastrow et al. (US 5,961,988, issued Oct. 1999) as applied to claims 17, 20, 23, 24, 26, 30, and 31, and further in view of Gross et al. (US 5,637,318, (hereinafter, the '318 reference), patented Jun. 1997).

The teachings of Stora and Zastrow et al. are delineated above. As to claim 18, the functional limitation of oxygen content four weeks after initial loading inherently would lie within the range of 25-40% upon loading according to the instant specification. For example, page 2 of the instant specification (paragraph 5) describes the oxygen loading in which oxygen gas within a broad range of partial pressures is bubbled through the carrier system with stirring at ambient temperature for a specified time period. Upon bubbling oxygen through the carrier composition as described, the oxygen presence necessarily would result in an oxygen quantity equal to or approximating the quantity instantly claimed.

Stora do not teach a quantitative value for oxygen loading in a perfluorinated hydrocarbon carrier as in the instant claim.

Gross et al. ('318) teach oxygen-laden fluorocarbons and fluorocarbon mixtures suitable for dermatological use (see abstract, in particular). Additionally, Gross et al. state that fluorocarbons are capable of transporting oxygen (see '318 reference, column 2, line 39) and with the aid of known oxygen gas solubilities, the vapor pressure (an inherent property), and the critical solubility temperature, the loading of fluorocarbons with oxygen can be adjusted by the skilled artisan (see '318 reference, column 4, lines 21-26).

Therefore, regarding claim 18, it would have been prima facie obvious to one of ordinary skill in the art to adjust the presence of oxygen in a fluorocarbon carrier for a dermatological application as suggested by Gross et al. in order to improve the oxygen carrying capacity of a topically applicable composition such

as the one taught by Stora. One would have been motivated to do so in order to optimize the benefits associated with oxygen delivery to the skin as evaluated according to the final product. Since this optimization process would have been routine procedure, one of ordinary skill in the art at the time the invention was made would have expected resulting success.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Zastrow et al. (US 5,961,988, issued Oct. 1999) as applied to claims 17, 20, 23, 24, 26, 30, and 31, and further in view of Gross et al. (US 5,643,601, (hereinafter, the '601 reference), patented Jul. 1997).

The teachings of Stora and Zastrow are delineated above. As to claim 22, Stora teach that the perfuming ingredients can belong to a variety of chemical classes including alcohols, esters, acetates, terpenic hydrocarbons, and essential oils of natural or synthetic origin (see column 5, lines 54-60).

Regarding claim 21, Stora does not expressly include a gelling or thickening agent in the carrier system. As to claim 22, Stora does not limit the carrier system oil base to one which is a vegetable oil, an ester, or a mixture thereof.

However, Gross et al. ('601) teach phospholipid-and fluorocarbon containing cosmetics to be formulated as gels, creams, lotions, etc. in order to supply adequate oxygen to the skin upon application (see abstract, in particular). Gross et al. teach that the fluorocarbons in this composition analogous to that of

Stora can be selected for oxygen gas solubility, partial vapor pressure, and lipid solubility according to the specific intended application ('601 reference, see column 3, lines 28-30). Specifically, Gross names perfluorodecalin as a rapid release oxygen carrier which also is embodied in the invention (see '601 reference, column 3, line 34; see also, column 4, Table 1). As to claim 21, Gross et al. teach the inclusion of hydroxyethyl cellulose (a thickening agent), in a gel mask formulation of the invention (see '601 reference, column 7, example 9). As to claim 22, Gross et al. teach jojoba oil and liquid paraffin as components in Example 5, a body lotion. One of ordinary skill in the art at the time of the invention would have recognized that jojoba oil is a liquid wax produced in the seed of the jojoba plant and is a mixture of wax esters desirably present in cosmetic and topical applications.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Stora and Gross et al. in order to maintain the benefits of the fluorocarbon formulation component (i.e., optimized oxygen incorporation and delivery) and to further optimize this oxygen carrier component in the analogous product resulting from this combination of teachings. The skilled artisan would have been motivated to optimize physical properties such as formulation thickness and therefore manageability by including a known gelling agent such as hydroxyethyl cellulose as is routine in the cosmetic arts and as is suggested in the disclosure of Gross et al., particularly since Gross et al. state a variety of cosmetically acceptable formulations such as gels, pastes, ointments, creams, lotions, etc (see '601

reference, column 4, lines 10-11). Similarly, the skilled artisan would have been motivated to implement jojoba oil into the topically applicable formulations on account of its commonly recognized and desirable properties such as being odorless and relatively shelf-stable when compared with other vegetable oils useful as cosmetic carriers, as taught by Gross et al.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stora (US 6,403,109) in view of Zastrow et al. (US 5,961,988, issued Oct. 1999), and Gross et al. (US 5,643,601) as applied to claims 17, 20, 23, 24, 26, 30, and 31 above and further in view of Pelle et al. (US 5, 811,083, patented Sep. 1998), and Nakanishi et al. (US 6,576,623 B1, patented Jun. 2003).

The teachings of Stora, Zastrow, and Gross are delineated above. Stora does not disclose the inclusion of tocopherol or a tocopherol derivative in the instantly prescribed quantity. It is noted that Gross et al. teach the inclusion of antioxidants such as a- tocopherol (see '601 reference, column 3, lines 66-67) in analogous perfluorodecalin-containing cosmetic compositions.

However, these references do not teach the instantly specified tocopherol derivatives in the instantly specified quantity. Nakanishi et al. teach silicone compounds useful in cosmetic applications wherein tocopheryl succinate is taught as a functional equivalent to a-tocopherol (see column 10, lines 58-60), and Pelle et al. specifically teach tocopherol derivatives for use in cosmetic compositions. Specifically, Pelle et al. disclose advantages of using tocopherol

derivatives for regulating skin aging and other disorders and suggest a most preferred quantity of 0.01 to 1.0 wt. % for topical applications (see column 7, lines 32-36). Further, one of ordinary skill would have been motivated to optimize this formulation component presence in order to impart desired properties to the final product. MPEP 2144.05 addresses the patentability of routine optimization procedures as addressed above.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute tocopheryl succinate as taught by Nakanishi for the a-tocopherol disclosed in the formulations of Gross et al. One would have been motivated to do so since these a-tocopherol and tocopheryl succinate have been shown in the prior art to be interchangeable and to have insubstantial differences both structurally and functionally. Likewise, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Pelle et al. with the teachings of Gross et al. in order to determine a desirable quantity of tocopherol derivative in a cosmetic formulation. Also, it would have been prima facie obvious to combine the teachings of Gross et al. and Stora and to utilize Gross' suggestion to include tocopherol or its derivative in a topically applicable perfluorodecalin-containing cosmetic composition. One would have been motivated to combine these teachings since Gross et al. teaches the advantage of avoiding auto-oxidation processes in other formulation components by adding an anti-oxidant such as alpha-tocopherol to a formulation analogous to that of Stora. Since Gross et al. does not specify an acceptable quantity, the skilled artisan would have been

motivated to look to Pelle et al. in order to determine a topically acceptable quantity of the tocopherol agent.

Response to Arguments

Applicant's arguments presented 1/10/2011 have been fully considered. As noted above, all rejections previously presented and not re-iterated herein are withdrawn. Applicant's positions against cited references are summarized and responded to as follows.

Regarding the rejection of claims 17, 20, 23, 24, 30, and 31 as being obvious over Stora in view of Zastrow, Applicant argues that a *prima facie* case of obviousness has not been established since Stora allegedly must suggest the desirability of the combination of the product of Zastrow with magnetically hard particles and asymmetrical lamellar aggregates from fluorocarbons and phospholipids wherein the aggregates are loaded with oxygen (see last full sentence on page 5 of 9 of Remarks); Applicant further argues that the combination was not obvious and "any other conclusion is impermissible hindsight" (see first paragraph, page 6 of 9 of Remarks). In reply, Applicant's argument has been considered but is not persuasive since the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art. See MPEP 2145 (III). Applicant's assertion of impermissible hindsight and argument that Stora and Zastrow are directed to

different objectives (paragraph 2, page 6 of 9 of Remarks) is not persuasive further because both Stora and Zastrow are both directed to cosmetics such as fragrances which were topically applicable. Applicant's additional proposed modifications of the cited reference (end of second paragraph, page 6 of 9 of Remarks) do not find basis in the rejections of record and are not the modifications proposed. As such, these proposed alternatives do not appear to be material to a finding of obviousness or an argument against the obviousness rejection of record.

Applicant argues that the quantity of fluorinated hydrocarbon in the prior art is outside the range of the instant claims (see last paragraph, page 6 through first paragraph, page 7 of 9 of Remarks). This position has been fully considered and is addressed above, in light of Applicant's amendment which clarifies and further limits the structure of the claimed formulation. For this reason, the rejection of claim 26 has been modified in light of the amended claims as addressed above.

Applicant argues that the partial pressure values taught by Zastrow are different from the partial pressure values instantly claimed. In reply, it is maintained that the Zastrow reference teaches the partial pressure to be between 80 mmHg and 300 mmHg; this range converts to a range of 106.64 mbar to 399.9 mbar. Although Applicant's unit conversion of the mPa units to mbar units appears also to be correct, the teaching remains that the range 80 mmHg to 300 mmHg is specified in the art, and this range overlaps with the range instantly claimed. The conversion factor 1.33322 x 10^-6 bar = 1umHg as

provided from the CRC Handbook was used to convert Zastrow's teaching of mmHg to the mbar units in the instant claims. Therefore, the relevance of the Zastrow reference is maintained for the reasons of record.

For these reasons, it is maintained that the limitations of the claims have been met by the Stora and Zastrow references, which one of ordinary skill in the art at the time the invention was made would have been motivated to combine in order to utilize the desirable oxygen pressure up to the saturation limit as taught by Zastrow et al.

Regarding the rejection of claim 18 over Stora and Zastrow and further in view of Gross, Applicant argues that the declaration under 37 C.F.R. 1.132 submitted February 10, 2010 includes results which demonstrate a surprising synergy which is due to the claimed system's silicone polymer. In reply, it is maintained that the results presented in the declaration do not demonstrate statistical significance of the results allegedly having synergy. For instance, results showing statistical significance generally give a calculated margin of error which conveys the likelihood that a hypothesis is unlikely to have happened merely by chance (*e.g.*, a critical "p-value"). Applicant's data show that the experiments may be replicated but do not provide any measure of significance for the average values presented. Further regarding this point, it appears that Applicant's arguments apply to the rejection of claim 18 and not claim 19 as stated at the bottom of the second paragraph on page 8 of 9 of Remarks.

Conclusion

No claims are found allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/Richard Schnizer/
Primary Examiner, Art Unit 1635